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(72) SANSALONE, S.N., CA
(71) SANSALONE, S.N., CA

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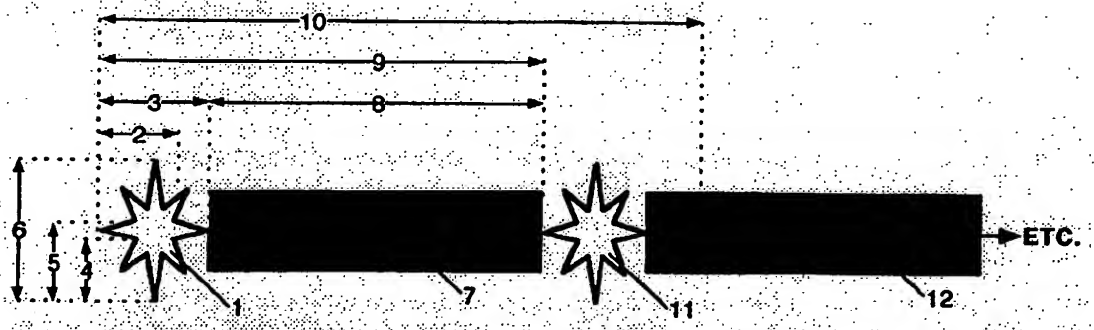
(54) APPAREIL DE PHOTOTHERAPIE ET METHODE POUR LE TRAITEMENT DE L'HYPERBILIRUBINEMIE

(54) PHOTOTHERAPY APPARATUS AND METHOD FOR HYPERBILIRUBINEMIA TREATMENT



(57) In apparatuses and methods for the medical treatment of hyperbilirubinemia, it is known to use phototherapy lamps in a manner that exposes the patient to an essentially steady stream of light. Even the "intermittent" variety of known phototherapy methods are characterized by steady exposure to light whereby the light remains continuously on during their relatively long "lights-on" segments of treatment, such a continuously-on segment lasting on the order of many minutes to several hours. In this invention, however, light is delivered to the patient instead in burst pulses greatly shortened in duration, down to tiny fractions of a second, to approach the mere nanoseconds-long time period actually required to cause the molecular-level therapeutic photoisomerization of bilirubin. Such flashes of light are then repeated only often enough to accommodate or match the actual bilirubin migratory rates of the particular tissue being targeted. The short-duration flashes spaced in time as far apart as possible in sequential cycling can thus reduce to a minimum total light irradiance dose, therefore helping to minimize the potential for phototoxic side effects. This in turn allows the use of greatly increased intensity of light for deeper penetration into patients' target tissue to allow a greater number of bilirubin molecules to simultaneously undergo molecular photoisomerization, all to the therapeutically advantageous effect of more rapid lowering of serum bilirubin levels. Even with such use of greatly-increased intensity of light, actual total irradiance dose to the patient can in fact still remain lower than with previously known phototherapy approaches since the invention so unprecedently eliminates exposure during strategic, extensive 'blackout' periods which the Applicant has discovered as being unnecessary for coverage by light exposure given the actual relationship of required time periods of bilirubin molecular geometric structure alteration by photoisomerization and bilirubin migration in target tissue. The light source used can be of virtually any safe type that includes in its emission sufficient energy levels in the appropriate wavelength range, while specifically a xenon flash tube embodiment would allow for particularly efficient electronic flashing of the light and also possesses the property of yielding a therapeutically optimal output emphasis around the blue wavelengths portion (400 to 500 nanometers) of the visible spectrum. In another embodiment based more on traditional phototherapy light sources, the short-duration flashes can be produced by various mechanical shutter or electrical means. Light delivery to relevant tissue in the patient can be accomplished by any of various external, internal, or surgical means.

PHOTOTHERAPY APPARATUS AND METHOD FOR HYPERBILIRUBINEMIA TREATMENT

ABSTRACT

In apparatuses and methods for the medical treatment of hyperbilirubinemia, it is known to use phototherapy lamps in a manner that exposes the patient to an essentially steady stream of light. Even the "intermittent" variety of known phototherapy methods are characterized by steady exposure to light whereby the light remains continuously on during their relatively long "lights-on" segments of treatment, such a continuously-on segment lasting on the order of many minutes to several hours. In this invention, however, light is delivered to the patient instead in burst pulses greatly shortened in duration, down to tiny fractions of a second, to approach the mere nanoseconds-long time period actually required to cause the molecular-level therapeutic photoisomerization of bilirubin. Such flashes of light are then repeated only often enough to accommodate or match the actual bilirubin migratory rates of the particular tissue being targeted. The short-duration flashes spaced in time as far apart as possible in sequential cycling can thus reduce to a minimum total light irradiance dose, therefore helping to minimize the potential for phototoxic side effects. This in turn allows the use of greatly increased intensity of light for deeper penetration into patients' target tissue to allow a greater number of bilirubin molecules to simultaneously undergo molecular photoisomerization, all to the therapeutically advantageous effect of more rapid lowering of serum bilirubin levels. Even with such use of greatly-increased intensity of light, actual total irradiance dose to the patient can in fact still remain lower than with previously known phototherapy approaches since the invention so unprecedently eliminates exposure during strategic, extensive 'blackout' periods which the Applicant has discovered as being unnecessary for coverage by light exposure given the actual relationship of required time periods of bilirubin molecular geometric structure alteration by photoisomerization and bilirubin migration in target tissue. The light source used can be of virtually any safe type that includes in its emission sufficient energy levels in the appropriate wavelength range, while specifically a xenon flash tube embodiment would allow for particularly efficient electronic flashing of the light and also possesses the property of yielding a therapeutically optimal output emphasis around the blue wavelengths portion (400 to 500 nanometers) of the visible spectrum. In another embodiment based more on traditional phototherapy light sources, the short-duration flashes can be produced by various mechanical shutter or electrical means. Light delivery to relevant tissue in the patient can be accomplished by any of various external, internal, or surgical means.

SPECIFICATION

This invention relates to phototherapy apparatuses and methods, most notably to their application in the medical treatment of hyperbilirubinemia, which presents most significantly in the pediatric condition of neonatal jaundice. Phototherapy aims to alter the problematic bilirubin chemistry of such infants by causing the photoisomerization conversion of certain dangerous isomers of bilirubin molecules into non-threatening isomers that will form upon exposure to light of sufficient energy level and of appropriate color, typically in the 425 to 475 nanometers wavelengths range.

It is common in neonatal phototherapy devices and processes to expose the patient to an essentially steady stream of light. Even in what is commonly known as "intermittent phototherapy" there is a characteristic steady exposure to light whereby the light remains continuously on during relatively long "lights-on" segments of treatment, such a continuously-on segment or so-called "pulse" lasting on the order of many minutes to several hours. Commonly used light sources include fluorescent tubes, quartz-halogen bulbs, or light-emitting diodes.

In a typical phototherapy treatment regimen, the newborn infant spends many hours or days under phototherapy lights, with varying degrees of physical separation from the mother.

It is known that therapeutic efficacy is dependent in part on the intensity of light and length of treatment, whereby increases in either factor would generally tend to improve efficacy. Such increases, however, also logically result in an increased total light irradiance dose to the patient with the consequential increase in potential for phototoxic side effects or other side effects. Therefore, it is considered that beyond a certain point increased efficacy by this means can also potentially be attended by decreased safety for the patient of phototherapy treatment, some controversial studies suggesting that even standard-intensity phototherapy may lead to light irradiance overdose complications, particularly for premature neonates. Thus, the safety of prior art phototherapy has been questioned on the basis of total light irradiance dose.

In part out of concern over the possibility of excessive irradiance dosing, prior art phototherapy has in actual fact been applied with relatively limited intensity or brightness of the light used, such brightness typically being kept near or below that of ordinary daylight, even in the case of newer, so-called "high-intensity" phototherapy light sources. As a result, therapeutic efficacy and speed efficiency have in part been limited by the prior art's limitation in brightness, since such limited light intensity produces proportionally limited penetration of light into patient tissue, and thereby limited photoisomerization of problematic bilirubin.

In some of the more severe patient cases, the aforementioned limitation in photoisomerization in turn still results in continuing high risk for the occurrence of dangerous complications such as kernicterus, extended lengths of hospital stays, consequential higher cost of treatment, longer separations of newborns from their mothers, and, where the phototherapy regimen is deemed too inadequate, use of risky blood exchange transfusions as a contingency that in itself sometimes directly causes death or additional morbidity for the infant as a side effect, such use of exchange transfusions continuing to occur with significant frequency despite use of prior art phototherapy.

Thus, phototherapy approaches of the prior art, with their still significantly limited light intensity capabilities, have produced only limited success towards the goals of preventing dangerous complications such as kernicterus without additional intervention being applied by risk-laden blood exchange transfusions employed when known phototherapy apparatuses and methods have been deemed inadequate to control dangerous bilirubin levels. On the other hand, questions have been raised concerning the safety of prior art phototherapy due to its extended-exposure, inherently high total light irradiance dosing, even with intermittent regimens. The prior art is

thereby caught in what may be described as a tug-of-war effect between seemingly incompatible, non-synergistic forces resulting in too little intensity alongside too much total exposure, where improving the factor of intensity has tended to worsen the other factor of total light irradiance dosing. Therefore, prior art hyperbilirubinemia phototherapy treatments, with their relative limitations in light intensity and limited reductions in total irradiance dose, are inefficient and unsatisfactory given the much greater practical potential that the Applicant has shown to exist through the novel apparatuses and methods he is now proposing.

The Applicant has found that the above-noted disadvantages of the prior art may be overcome by providing a phototherapy apparatus and method whereby light is delivered to the patient in flashes; burst pulses greatly shortened in duration down to tiny fractions of a second, to approach the mere nanoseconds-long time period actually required to cause the molecular-level therapeutic photoisomerization of bilirubin. Such flashes of light are then repeated only often enough to accommodate or match the actual bilirubin migratory rates of the particular tissue being targeted. The short-duration flashes spaced in time as far apart as possible in sequential cycling eliminate unnecessary exposure and can thus reduce to a minimum total light irradiance dose, therefore helping to minimize the potential for phototoxic side effects. These combined factors in turn permit the use of greatly increased intensity of light for deeper penetration into, and more extensive coverage of, patients' target tissue to cause a greater number of bilirubin molecules to simultaneously undergo molecular photoisomerization, all to the therapeutically advantageous effect of more rapid lowering of serum bilirubin levels. Even with such use of greatly-increased intensity of light, actual total irradiance dose to the patient can in fact still remain much lower than with previously known phototherapy approaches since the invention so unprecedently eliminates exposure during strategic, extensive 'blackout' periods which the Applicant has discovered as being unnecessary for coverage by light exposure given the actual relationship of required time periods of bilirubin molecular geometric structure alteration by photoisomerization and bilirubin migration in target tissue. Therefore, the Applicant has found a way to simultaneously greatly increase intensity while greatly decreasing total irradiance dose as compared to all prior art attempts. This represents a dramatic reversal of the aforementioned side effect trend that has been an expressed concern in medical research, as well as an opportunity for increases in phototherapy efficacy which has long been a desired goal in the medical field. The present invention offers improvement to both the efficacy and safety of phototherapy treatment.

By safely increasing efficacy of phototherapy treatment for hyperbilirubinemia, the present invention reduces to an unprecedented degree the chances for development of threatening medical complications from severe jaundice, such as kernicterus. This will serve to reduce the frequency with which risky exchange transfusions are prescribed. Such efficiency of treatment and potential to shorten total treatment time will also help reduce length of hospital stays as well as reduce related health care expenses. It can further mitigate separation times of newborn from mother, thereby reducing postnatal emotional stress particularly to the mother and increasing bonding opportunity between a newborn infant and its parents. This is accomplished even in simpler embodiments of the invention where intensity is not necessarily increased but 'blackout periods', intermittent time periods during which the patient is not being exposed to therapeutic light, are still greatly increased proportionally to actual exposure times as compared with the prior art, such extended blackout periods affording more direct early bonding opportunities between a newborn and its family. Also, use of this invention affords opportunity to reduce side effects of the non-photoisomerization phototoxic or other photodynamic type, as well as to avoid any photoisomerization phototoxic side effects dependent on light wavelengths outside the therapeutic range for bilirubin photoisomerization, providing that the embodiment's light emission characteristics are made to be of sufficiently narrow bandwidth, by filtration or otherwise, to prevent exposing the patient to non-therapeutic wavelengths of light.

In drawings and charts which help illustrate embodiments of the invention, Figure 1 is a chart diagrammatically representing the progressive process steps of a preferred embodiment. Figure

2a for a similar embodiment is a simplified chart representationally graphing the relationship between the three key process components of flash pulse duration, flash pulse intensity, and blackout period within the cycle-time of flash pulse repetitions; plus for comparative purposes Figure 2b representing the relevant prior art in comparison chart form. It is noted that Figures 1 and 2a for practical reasons are not necessarily drawn to scale. Figure 3 is a further simplified chart clarifying and detailing the chronological aspects and consecutive steps of an embodiment of the process or method. Figure 4 in a top view illustrates another embodiment where a lens focuses light, from a xenon tube, for delivery to a patient through a fiber optic blanket which is shown in its unwrapped state. Figure 5 is a largely diagrammatic elevation partly in section of one apparatus embodiment incorporating an opaque tent structure. Figure 6 is a largely diagrammatic elevation partly in section of another device embodiment incorporating light sources placed in between an internally reflective opaque tent structure and the patient.

The process diagrammatically illustrated with symbols in Figure 1 comprises a first step of a light flash burst 1 where the width 3 represents diagrammatically the time duration of the flash or pulse and the height 6 represents diagrammatically the amplitude or intensity of the light at the point of transition from air to patient tissue, as if such symbol 1 were derived dimensionally from an x-y axis graph with time running along the bottom axis from left to right and intensity running on the left axis from bottom to top. The second step manifests as a blackout phase 7 during which time period 8 no phototherapy light is delivered to the patient within a cycle-time 9 that in itself is the sum of pulse duration 3 plus blackout period 8, accommodating the migratory rate 10 of bilirubin in targeted tissue, such rate 10 being overlapped by sequential flash/pulse bursts 1 and 11 in the illustrated embodiment, and extending into the next sequential blackout period 12, in order to accommodate a possible margin of error from variations in the actual migratory period 10. The amplitude or intensity 6 of the light needs to be of sufficient energy so that when its energy level drops to intensity 5 due to light loss during transmission through patient tissue that intervenes the light's path to a targeted bilirubin molecule, the remnant intensity level 5 is still sufficient to cause the intended photoisomerization of targeted bilirubin molecules which have a threshold energy requirement 4, where 4 and 5 are as measured at the specific bilirubin molecule site. The level requirement of delivered light intensity 6, therefore, is dependent upon the types and depths of intervening tissue such as skin, adipose tissue, etcetera relative to the targeted bilirubin. The actual practical baselines for intensity 6 are obviously best determined or refined by empirical clinical study and depend heavily upon the specific tissue and tissue depths being targeted for the particular patient's hyperbilirubinemia case. The advantage with the present invention is that intensity can be greatly increased over the prior art to an effect whereby sufficient energy levels of light reach deeper tissue than previously available, without increasing total light irradiance dose by virtue of the novel combination of sufficiently shortened pulse duration 3 and sufficiently long blackout periods 8 between flashes within the cycle-time 9.

The flash/pulse duration 3 is ideally shortened as much as possible towards the mere nanoseconds-long time requirement for the photoisomerization of bilirubin. Such flash/pulse duration 3 can be 1/1000th of a second in one embodiment, such being a common flash duration produced by common xenon flash tube based light sources. The shorter the flash duration the better for reducing unnecessary irradiance dose, provided that the duration is at least as long as the threshold time period 2 required to cause the occurrence of photoisomerization of targeted bilirubin taking into consideration its molecular properties, geometrical structure, and dynamic activities, including any need to accommodate molecular rotation or attitude relative to incoming photons of light. (To further accommodate the like of such factors it would be possible to deliver a series of closely-spaced flashes together before each blackout period 8, where each cycle-time 9 would comprise additional flash components whereby the group of such closely-spaced flashes over a period of minutes, seconds, or a fraction of a second, would then be followed by the blackout period 8. This optionally could be viewed as a minor cycle-time within an overall process cycle-time.) Although individual flash or pulse durations exceeding small fractions of a second may be required, being easier to form particularly in the case of a simple mechanical

shutter type of pulsing method, such longer durations can unnecessarily increase irradiance dose and must in any case always be kept below the durations of the prior art for a given intensity in order to gain the novel advantage of decreased total irradiance dose with retained or improved efficacy. Prior art 'pulse' durations range typically in the 15 minutes to several hours range. What is proposed by preferred embodiments of the present invention is that the pulse durations remain small enough to be measured in units of seconds, and more preferably in tiny fractions of a second. It is an object of this invention that flash pulse duration be shortened enough to improve safety potential and thereby allow the option of using greater intensity than previously possible for a given total irradiance dose.

The flash/pulse energy intensity 6 can be set according to one of three main options.

In the first option, where there are improvements to both the efficacy and safety of treatment, the flash/pulse light intensity 6 is significantly greater than in the prior art, yet total irradiance dose is kept below that of the prior art by virtue of the combination of sufficiently short flash/pulse duration 3 and sufficiently long cycle-time 9. This first option is considered by the Applicant to be generally the most valuable approach.

In the second option, where there is need to improve only safety potential, for example in some of the less severe cases of hyperbilirubinemia, the intensity 6 remains essentially the same as in the prior art yet total irradiance dose is kept below that of the prior art by virtue of the combination of sufficiently short flash/pulse duration 3 and sufficiently long cycle-time 9.

In the third option, where there is a need to increase only efficacy, and treatment safety potential can be justifiably compromised to a degree in an effort to more successfully treat a particularly extreme severe case of hyperbilirubinemia, where the priority need exists to increase efficacy above and beyond the already improved capabilities of the first option, the much higher light intensity capabilities of xenon tubes or similarly intense light sources are exploited so that light intensity is significantly increased even over that of the first option to the point that, despite maximally shortened flash/pulse duration 3 and maximally lengthened cycle-time 9, total irradiance dose has been allowed to rise over that of the prior art as a last resort contingency where not allowing so would offer only those other non-phototherapy alternatives that are of even greater risk to the patient's health due to their more serious potential side effects.

Stating these options in another way, the invention actually offers a choice of either one or both of the following advantages over the prior art: 1) increased light intensity, which improves efficacy through more rapid reduction in dangerous bilirubin, and 2) decreased total light irradiance dose, which holds the potential to lower risk from potential phototoxic or other side effects from phototherapy. On the first advantage, intensity can be increased, for example with the use of xenon tubes in one embodiment, to the degree of being hundreds of times as intense than in the prior art. On the second advantage total light irradiance dose can be reduced in one embodiment to the point of being less than one-millionth the amount of prior art methods.

The greatly increased intensity of the said first advantage offers unprecedented opportunities for deeper light penetration through intervening tissue occupying the light path, for a more extensive simultaneous coverage of the circulatory system and other bilirubin-holding/transporting tissues or organs. Intensity, and thereby penetration, does not have to be limited out of the concerns for irradiance dose that exist with the prior art since the present invention offers a novel method of reducing total irradiance dose through the combination of uniquely short flash/pulse duration 3 and sufficiently long cycle-time 9. A range of optional variables in intensity, cycle-time, flash or pulse duration, and other factors can customize specific treatment approaches in order to achieve, for the particular patient case, the optimal effect on rapidity of bilirubin-lowering, in order to avoid dangerous medical complications and to effect the bypassing of exchange transfusions.

As explained above, the invention's reduction in flash/pulse duration 3 combined with sufficiently long cycle-time 9 can secure a greater effect for the same or less amount of irradiance dose, and in some embodiments the reduction in total light irradiance dose can be on the order of one-millionth that of the prior art. This example is arrived at by simple math where, during a 24-hour treatment period, using a 1-hour cycle-time and a 1/1000th of a second flash duration, the patient is exposed to light for a total of only 0.024 seconds. If the intensity is 180%, or almost double, that of the best prior art intensity, then there would be only one-millionth of the total irradiance dose for the entire treatment with the present invention as compared to the prior art being used in a conventional intermittent phototherapy regimen where the lights are off for half of the treatment period, all the while the present invention offering improved efficacy from almost double the intensity of delivered light.

The irradiance dose-reducing benefits of the present invention are manifest in any flash or pulse duration in the range significantly below that of prior art 'pulse' durations (i.e. intermittent intervals), but as demonstrated in the above example, very dramatic reductions in irradiance dosage are achievable when shortening flash/pulse duration 3 to a tiny fraction of a second. In the attempt to show diagrammatically these tiny fractions of a second of duration 3, it became necessary in the present drawings that elements of the same figure not be in proportion since a different proportion was indispensable for the clarity of the figure. For example, in the preferred embodiment above with a 1/1000th second flash duration and 1-hour cycle-time, if that flash duration 3 were represented on a graph as a line 10 mm long, the 1-hour cycle time would then proportionally have to be drawn as a 36 km long line on the graph, obviously beyond the capability of proportional representation on standard paper sizes for patent drawings. But in striking contrast it would be a very simple matter with the much simpler prior art to make such drawings proportional, where if a typical 1-hour 'pulse' lights-on segment were represented as a line 10 mm in length, then the 1-hour cycle-time would be represented simply by another 10 mm long line. Stated another way, the invention's pulse duration in this example is only 0.0000003% of its cycle-time, whereas the prior art's is 50.0% of its cycle-time.

As explained previously, matching pulse cycling times to bilirubin migratory rates maximizes safety and convenience, that is when combined with the novel shortened pulse durations of the present invention. Migratory rates/periods are highly variable between different tissue types, ranging from hours in the case of some skin to seconds or fractions of a second in some circulatory system components that can now be more realistically targeted through the unprecedently higher intensity levels now more safely available from some embodiments of the present invention. (A migratory period is defined here as the limited span of time beginning specifically when a bilirubin molecule enters into, and ending specifically when the bilirubin molecule moves out of, the tissue and/or organ zone within range of photoisomerization-sufficient levels of therapeutic light provided by a phototherapy apparatus/method yielding a given intensity of light.) Besides the dramatically higher intensity levels afforded, another advantage of using a xenon-tube type of light source would be its ability to be controlled simply and accurately for cycle-time across the aforementioned range of migratory periods by a practical, inexpensive means using microchip technology. The choice of targeted tissue types, including their targeted depths, determines the minimum required light intensity and which of the different options for blackout periods would be incorporated, all of which further depend on case severity of hyperbilirubinemia and the safety or convenience needs of the particular patient with respect to age and other medically significant conditions.

In certain more intensive regimens it would be necessary, due to the rapid cycling rates, for the patient to maintain minute-to-minute and hour-to-hour interface with the invention's light delivery apparatus. A fiber optic blanket 13 could be particularly useful in such a case due to its ability to keep baby and mother together with only an apparatus blanket partly between the two. In such an embodiment a xenon tube 14, controlled according to the invention optionally for duration, cycle-time, and intensity by a computer 15, could be interfaced with the fiber optic

bundle 17 by a condenser lens 16 that focuses the light efficiently into the fiber optic bundle 17 for dispersion to the patient's skin through the blanket portion 13.

In certain less-intensive regimens where the infant does not have to remain under lights for extended periods as in cycle-times of 30 minutes or 1 hour for example, with each flash duration being just a fraction of a second, the infant 18 lying down on a bed, pad, or platform 19 can simply be exposed to flashes from a simple electronic flash unit 20, even of the common photographic equipment type, mounted above the pad on which the infant lies. To achieve what is medically referred to as a double phototherapy effect, following each anterior exposure the infant can simply be turned over for flashing of its posterior side, or transparent/translucent material can be used for platform 19 for simultaneous exposure from above and below by employing an additional light source. If a more intense regimen requires increased flashing complexity, and specific eye shielding is considered undesirable, a neck-down opaque tent structure or garment 21, optionally with an inner reflective surface 22, can ensure that the patient's eyes are protected from the bright light 23. The light source 20 can be placed at the opposite-to-patient end of the light-occluding structure 21, or the light source 24 can be placed in-between the light-occluding structure 21 and patient 18, such patient optionally being enveloped by an internally reflective garment 21 that extends all around the patient's body below the head, with ports 25 to enable cradling of an infant with the caregiver's arms. In all cases, the light source 14, 20, or 24 is ideally filtered as necessary to limit light delivery to only those wavelengths that are therapeutic to the patient. Also, the said light sources can be comprised of either a single or multiple sources working as a bank of lights, the goal ideally always being to achieve maximum and/or even illumination of the patient. Some focused or parallel-path light sources, such as from lasers, could also be useful, including where a localized beam of light would be practical for specific tissue targeting or even entry at the apparatus level, for instance into a narrow optical light delivery system like a fiber optic bundle.

The Applicant has discovered and proposes many other possible ways in which the inventive ideas noted above can be applied, some of which are described below as more extreme applications that may be useful in the treatment of certain more severe cases of hyperbilirubinemia where the most rapid possible lowering of serum bilirubin levels is critical to the patient's life or health.

A probing light flash/pulse unit could be surgically positioned at a location where problematic serum bilirubin could be more quickly and/or more extensively addressed in highly acute conditions. It would even be possible as a short-term or longer-term arrangement to surgically implant a self-contained apparatus, for example in cases where doing so could reduce the chance of infection as compared to the non-self-contained surgical approach above. It would even be possible to power the capacitors of such a device, in the case of a xenon tube for example, through closed skin by induction from an external charger. There would be many possible site options for a probe, whether to illuminate organs, vessels, or other tissue from their own exteriors, or from their interior, including the concept of light-irradiating blood directly inside the circulatory system. Such a self-contained surgical implant may be found to be of particular value to patients suffering from the very rare disease Crigler-Najjar Syndrome in which very long-term phototherapy is required to be an ongoing part of their lives.

In another embodiment it would be conceivable to position a phototherapy device inside the gastrointestinal system to light-expose a certain type and phase of bilirubin before it gets re-absorbed through the intestinal wall into the blood stream, either with an externally-connected probing pulse unit, or self-contained units that are set on a course through the GI at appropriate intervals, or a single one of the latter that is remote-controlled.

It would also be possible to apply phototherapy in utero for critical prenatal conditions arising from very severe Rh sensitization where maternal liver processes are not sufficient to prevent

serious problems prenatally such as hydrops fetalis and other fetal complications of Rh sensitization . It is conceivable that the light be transmitted through the amniotic sac or uterus wall, targeting the baby's back by employing ultrasound monitoring for optimal positioning to minimize the risk of eye exposure, taking into consideration any effects of light reflection off of other tissue in the area.

Returning to phototherapy that is administered preferably external of the body, it would be possible to target short-migratory-rate bilirubin in certain components of the circulatory system that are well-positioned, like pulse-monitoring sites, and of sufficient translucence to facilitate a very quick and efficient delivery of light to an extensive flow of bilirubin particularly in unprecedented high intensity form.

Depending on the light intensity and the light-transmission properties of liver tissue and that region in general, it could be possible to cause bilirubin photoisomerization early in the process that otherwise leads to kernicterus, the goal being a faster, more efficient prevention of bilirubin deposition on nervous system tissue. The same process could be applied towards other relevant organ sites.

Various means could be employed to effect a pulsing or flashing of the light, whether by electronic, mechanical, or electrical means. It would also be possible to induce the flash effect by transmitting the light through an offset double polarizing filter that acts as a light shutter, with a between-the-filters spark triggering means to create the momentary opportunity of major light transmission through the filters in the form of a flash.

Some of the ideas proposed above could also be applied with conventional phototherapy's steady light and still remain as unique over the prior art by combination with the unprecedented process components, but the Applicant also teaches that light delivery for the photoisomerization of bilirubin in the treatment of hyperbilirubinemia with maximum light intensity and/or minimum total irradiance dose is most efficiently accomplished by utilization of unprecedently shortened flashes or pulses of light, combined with cycle-time rates that efficiently accommodate bilirubin migratory rates for targeted patient tissue, both in the conventionally-targeted slower-migratory-rate tissues, and in the faster-migratory-rate tissues and organs discussed in this Application.

CLAIMS

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A phototherapy method whereby the light is delivered as a burst or pulse or flash of light.

2. The phototherapy method of Claim 1 whereby the burst or pulse of light has a duration that is less than that of the prior art.

3. The phototherapy method of Claim 2 whereby the burst or pulse of light has a duration less than 1 minute in length.

4. The phototherapy method of Claim 3 whereby the burst or pulse of light has a duration less than 1 second in length.

5. The phototherapy method of Claim 4 whereby the burst or pulse of light has a duration less than 0.5 seconds in length.

6. The phototherapy method of Claim 5 whereby the burst or pulse of light is a flash with a duration less than 0.1 seconds in length.

7. The phototherapy method of Claim 6 whereby the burst or pulse of light is a flash with a duration less than 0.01 seconds in length.

8. The phototherapy method of Claim 7 whereby the burst or pulse of light is a flash with a duration less than 0.001 seconds in length.

9. The phototherapy method of Claim 8 whereby the burst or pulse of light is a flash with a duration less than 0.0001 seconds in length.

10. The phototherapy method of Claim 9 whereby the burst or pulse of light is a flash with a duration less than 0.00001 seconds in length.

11. The phototherapy method of Claim 10 whereby the burst or pulse of light is a flash with a duration less than 0.000001 seconds in length.

12. The phototherapy method of Claim 11 whereby the burst or pulse of light is a flash with a duration less than 0.0000001 seconds in length.

13. The phototherapy method of Claim 12 whereby the burst or pulse of light is a flash with a duration less than 0.00000001 seconds in length.

14. The phototherapy method of Claim 13 whereby the burst or pulse of light is a flash with a duration less than 0.000000001 seconds in length.

15. The phototherapy method of Claim 14 whereby the burst or pulse of light is a flash with a duration less than 0.0000000001 seconds in length.

16. The phototherapy methods of Claims 1 - 15 whereby the light is directed for the photoisomerization of bilirubin.

17. The phototherapy methods of Claims 1 - 16 whereby the light is directed for the treatment of hyperbilirubinemia.

18. The phototherapy methods of Claims 1 - 17 whereby the light is directed for the treatment of hyperbilirubinemia in neonates.

19. The phototherapy methods of Claims 1 - 18 whereby multiples of said light bursts or pulses or flashes are repeated in sequence.

20. The phototherapy method of Claim 19 wherein said repetition or repetitions occur at a rate where the cycle-time is greater than the light burst or pulse or flash duration time.

21. The phototherapy method of Claim 20 wherein said cycle-time is greater than 0.001 seconds in length.

22. The phototherapy method of Claim 21 wherein said cycle-time is greater than 0.01 seconds in length.

23. The phototherapy method of Claim 22 wherein said cycle-time is greater than 0.1 seconds in length.

24. The phototherapy method of Claim 23 wherein said cycle-time is greater than 1 second in length.

25. The phototherapy method of Claim 24 wherein said cycle-time is greater than 10 seconds in length.

26. The phototherapy method of Claim 25 wherein said cycle-time is greater than 100 seconds in length.

27. The phototherapy method of Claim 26 wherein said cycle-time is greater than 1,000 seconds in length.

28. The phototherapy method of Claim 27 wherein said cycle-time is greater than 10,000 seconds in length.

29. The phototherapy method of Claim 28 wherein said cycle-time is greater than 100,000 seconds in length.

30. A phototherapy method whereby the delivered light remains continuously on for a period less than that of the prior art.

31. The phototherapy method of Claim 30 whereby the delivered light remains continuously on for less than 1 minute at a time.

32. The phototherapy method of Claim 31 whereby the delivered light remains continuously on for less than 30 seconds at a time.

33. The phototherapy method of Claim 32 whereby the delivered light remains continuously on for less than 3 seconds at a time.

34. The phototherapy method of Claim 33 whereby the delivered light remains continuously on for less than 1 second at a time.

35. The phototherapy method of Claim 34 whereby the delivered light remains continuously on for less than 0.1 seconds at a time.

36. The phototherapy method of Claim 35 whereby the delivered light remains continuously on for less than 0.01 seconds at a time.

37. The phototherapy method of Claim 36 whereby the delivered light remains continuously on for less than 0.001 seconds at a time.

38. The phototherapy method of Claim 37 whereby the delivered light remains continuously on for less than 0.0001 seconds at a time.

39. The phototherapy method of Claim 38 whereby the delivered light remains continuously on for less than 0.00001 seconds at a time.

40. The phototherapy method of Claim 39 whereby the delivered light remains continuously on for less than 0.000001 seconds at a time.

41. A phototherapy method characterized by very-short-duration burst or flash pulses of high-intensity light at cycling rates matched to bilirubin migratory rates of targeted tissue.

42. The phototherapy method of Claim 41 whereby the flash or pulse duration is long enough to cover the time period of rotation to allow geometrically efficient entry of sufficient photon energy into targeted bilirubin molecules to cause photoisomerization, but with flash or pulse durations shorter than durations used in conventional phototherapy methods.

43. A phototherapy method whereby light exposure is not continuously steady whereby the continuous exposure is less than the pulse duration of conventional medical phototherapy units for the treatment of hyperbilirubinemia.

44. The phototherapy method of Claim 43 whereby the pulse duration is shortened to approach the minimum light exposure duration required for the photoisomerization of bilirubin.

45. The phototherapy method of Claim 44 whereby the pulse duration is less than 1 minute.

46. The phototherapy method of Claim 45 whereby the pulse duration is less than 1 second.

47. The phototherapy method of Claim 46 whereby the pulse duration is less than 0.1 seconds.

48. The phototherapy method of Claim 47 whereby the pulse duration is less than 0.01 seconds.

49. The phototherapy method of Claim 48 whereby the pulse duration is less than 0.001 seconds.

50. The phototherapy method of Claim 49 whereby the pulse duration is less than 0.0001 seconds.

51. The phototherapy method of Claim 50 whereby the pulse duration is less than 0.00001 seconds.

52. The phototherapy method of Claim 51 whereby the pulse duration is less than 0.000001 seconds.

53. The phototherapy method of Claim 52 whereby the pulse duration is less than 0.0000001 seconds.

54. The phototherapy method of Claim 53 whereby the pulse duration is less than 0.00000001 seconds.

55. The phototherapy method of Claim 54 whereby the pulse duration is less than 0.000000001 seconds.

56. The phototherapy methods of Claims 1 - 55 whereby flashes are grouped together in concentration within a minor part of the cycle-time in order to accommodate any light path vector need of bilirubin molecules to allow photoisomerization, or to accommodate any rotational dynamics of bilirubin molecules to allow photoisomerization to occur.

57. A phototherapy device comprising a light source and an electronic pulsing means whereby the pulse duration is less than that of conventional phototherapy devices and methods.

58. The phototherapy device of Claim 57 whereby the pulse duration is less than 1 minute.

59. The phototherapy device of Claim 58 whereby the pulse duration is less than 30 seconds.

60. The phototherapy device of Claim 59 whereby the pulse duration is less than 3 seconds.

61. The phototherapy device of Claim 60 whereby the pulse duration is less than 1 seconds.

62. The phototherapy device of Claim 61 whereby the pulse duration is less than 0.1 seconds.

63. The phototherapy device of Claim 62 whereby the pulse duration is less than 0.01 seconds.

64. The phototherapy device of Claim 63 whereby the pulse duration is less than 0.001 seconds.

65. The phototherapy device of Claim 64 whereby the pulse duration is less than 0.0001 seconds.

66. The phototherapy device of Claim 65 whereby the pulse duration is less than 0.00001 seconds.

67. The phototherapy device of Claim 66 whereby the pulse duration is less than 0.000001 seconds.

68. The phototherapy device of Claim 67 whereby the pulse duration is less than 0.0000001 seconds.

69. The phototherapy device of Claim 68 whereby the pulse duration is less than 0.00000001 seconds.

70. The phototherapy device of Claim 69 whereby the pulse duration is less than 0.000000001 seconds.

71. The phototherapy methods or devices of Claims 1 - 70 whereby the light source used is an electronic flash unit.

72. The phototherapy methods or devices of Claims 1 - 70 whereby the light source used is a gas tube.

73. The phototherapy methods or devices of Claims 1 - 71 whereby the light source used is a xenon tube type.

74. The phototherapy methods or devices of Claims 1 - 70 whereby the light source used is light-emitting diodes.

75. A phototherapy device comprising an electronic flash unit adapted for use as a phototherapy instrument.

76. The phototherapy device of Claim 75 whereby the use is in the treatment of hyperbilirubinemia.

77. The phototherapy device of Claim 76 whereby the use is in the treatment of neonates.

78. A phototherapy device and method incorporating a light source whereby its light exposure to the patient is pulsed intermittently by means of a mechanical shutter or by means of electrical means whereby in the latter the pulse is induced by transmitting the light through an offset double polarizing filter that acts as a light shutter, with a between-the-filters spark triggering means that provides the momentary allowance of a majority of light to pass completely through both filters.

79. The phototherapy device and method of Claim 78 whereby said pulse has a duration less than that of conventional phototherapy methods of the prior art.

80. The phototherapy device and method of Claim 79 whereby said pulse has a duration less than 1 minute.

81. The phototherapy device and method of Claim 80 whereby said pulse has a duration less than 30 seconds.

82. The phototherapy device and method of Claim 81 whereby said pulse has a duration less than 3 seconds.

83. The phototherapy device and method of Claim 82 whereby said pulse has a duration less than 1 second.

84. The phototherapy device and method of Claim 83 whereby said pulse has a duration less than 0.1 second.

85. The phototherapy device and method of Claim 84 whereby said pulse has a duration less than 0.01 second.

86. The phototherapy device and method of Claim 85 whereby said pulse has a duration less than 0.001 second.

87. The phototherapy device and method of Claim 86 whereby said pulse has a duration less than 0.0001 second.

88. The phototherapy device and method of Claim 87 whereby said pulse has a duration less than 0.00001 second.

89. The phototherapy device and method of Claim 88 whereby said pulse has a duration less than 0.000001 second.

90. A phototherapy method and device comprising a probing light-producing unit surgically positioned at a location where targeted molecules subject to photoisomerization could be more directly irradiated.

91. The phototherapy method and device of Claim 90 comprising a surgically implanted, self-contained phototherapy apparatus.

92. The phototherapy method and device of Claim 91 incorporating a xenon tube as the light source.

93. The phototherapy method and device of Claim 92 whereby capacitors or other energy-holding means are charged through closed skin by the process of electrical induction from an external charging means.

94. The phototherapy methods and devices of Claims 90 - 93 as applied to the treatment of hyperbilirubinemia.

95. A phototherapy method whereby light is made to irradiate blood directly inside the circulatory system.

96. A phototherapy method whereby light is made to irradiate the inside of the gastrointestinal system directly or indirectly.

97. The phototherapy method of Claim 96 whereby self-contained phototherapy units are set on a course through the gastrointestinal system, the transport system being gravity and/or peristalsis and/or mechanical propulsion remote-controlled externally.

98. A phototherapy method whereby light therapy is administered in utero in cases of severe Rh sensitization in order to prevent problems prenatally such as hydrops fetalis and other fetal complications of Rh sensitization.

99. The phototherapy method of Claim 98 whereby the light is transmitted through the amniotic sac or uterus wall.

100. The phototherapy method of Claim 99 in which the baby's back is targeting by employing ultrasound monitoring for positioning to minimize the risk of eye exposure.

101. A phototherapy method incorporating light of significantly higher intensity than in conventional phototherapy units of the prior art, whereby targets are set on short-migratory-rate bilirubin in components of the circulatory system that are well-positioned relative to the patient's exterior, and of sufficient translucence to facilitate this very quick and efficient delivery of light to an extensive and rapid flow of bilirubin not previously accessible for photoisomerization from conventional phototherapy units.

102. A phototherapy method incorporating light of higher intensity than in conventional phototherapy units and targeting bilirubin photoisomerization in the patient's liver to effect an earlier, faster, and more efficient prevention of bilirubin deposition on nervous system tissue.

103. A phototherapy method utilizing unprecedently shortened flashes or pulses of light, combined with cycle-time rates that efficiently accommodate bilirubin migratory rates for targeted patient tissue.

104. A phototherapy process whereby light is delivered to the patient in burst pulses greatly shortened in duration, down to tiny fractions of a second, to approach the mere nanoseconds-long time period actually required to cause the molecular-level therapeutic photoisomerization of bilirubin.

105. The phototherapy process of Claim 104 whereby said burst pulses or flashes of light are repeated.

106. The phototherapy process of Claim 105 whereby said repetitions are repeated only often enough to accommodate or match the actual bilirubin migratory rates of the particular tissue being targeted.

107. The phototherapy process of Claim 106 whereby the short-duration flashes are spaced in time as far apart as possible in sequential cycling in order to maintain efficacy of bilirubin photoisomerization in targeted tissue but reduce to a minimum total light irradiance dose, therefore helping to minimize the potential for phototoxic side effects.

108. The phototherapy process of Claim 107 whereby intensity of light greater than that of conventional phototherapy units is incorporated for deeper penetration into patients' target tissue to allow a greater number of bilirubin molecules to simultaneously undergo molecular photoisomerization, and to effect more rapid lowering of serum bilirubin levels.

109. The phototherapy process of Claim 108 whereby even with such use of greatly-increased intensity of light, actual total irradiance dose to the patient remains lower than with conventional phototherapy devices and methods.

110. The phototherapy process of Claim 109 whereby said lower irradiance dose is effected by extensive blackout periods unnecessary for coverage by light exposure given the actual relationship of required time periods of bilirubin molecular geometric structure alteration by photoisomerization and bilirubin migration in target tissue.

111. The phototherapy methods, processes, or devices of Claims 1 - 110 whereby the light source used is of a relatively safe type that includes in its emission sufficient energy levels in the appropriate wavelength range to cause intended therapeutic photoisomerization of bilirubin.

112. The phototherapy methods, processes, or devices of Claim 111 incorporating a xenon flash tube as the light source.

113. The phototherapy methods, processes, or devices of Claim 112 whereby the xenon tube is electronically flashed.

114. The phototherapy methods, processes, or devices of Claims 1 - 113 incorporating the use of a tented, light-occluding structure to protect the eyes of a patient and caregivers.

115. The phototherapy methods, processes, or devices of Claims 1 - 114 incorporating the use of a light-occluding garment structure enclosing the patient's body below the head or neck and including legs to maximize irradiated surface area and protect the eyes of a patient and caregivers.

116. The phototherapy methods, processes, or devices of Claims 114 and 115 whereby the light-occluding structure possesses an inner light-reflective surface.

117. The phototherapy methods, processes, or devices of Claims 114 to 116 whereby the light source is placed between the patient and said inner reflective surface of said light-occluding structure to provide either a combination of direct and reflected irradiation of a patient, or just reflected irradiation.

118. The phototherapy methods, processes, or devices of Claims 114 to 117 wherein a port or ports are provided to accommodate caregiver's arms or a mechanical platform structure in a role of supporting an infant patient.

119. The phototherapy methods, processes, or devices of Claims 1 to 118 whereby multiple light sources are incorporated for more even or more intense irradiation of the patient's surface area.

120. A phototherapy method characterized by very-short-duration burst pulses of high-intensity light at cycling rates matched to bilirubin migratory rates.

121. A phototherapy apparatus and method comprising a light source producing unprecedented very-short-duration sequential burst pulses of high-intensity light.

122. The phototherapy apparatus and method of Claim 121 whereby such pulses are greatly shortened to a mere flash approaching the actual nanoseconds-long time period required for the chemical photoisomerization of bilirubin to actually occur.

123. The phototherapy apparatus and method of Claim 122 whereby each such flash burst is separated from the next, spaced apart in time.

124. The phototherapy apparatus and method of Claim 123 whereby said separation and spacing closely matches or efficiently accommodates the migratory rate of bilirubin characteristic for the particular tissue being targeted by the phototherapy, to provide maximum therapeutic light intensity with minimum practical total light irradiance dose, or maximum efficacy with minimum potential for safety compromises.

125. A phototherapy apparatus and method whereby therapeutically optimal intensity levels of light are delivered as a sequence of intermittent burst-type pulses, each shortened in duration to a minimum ideally just exceeding the mere nanoseconds-long light exposure requirement for effecting photoisomerization of bilirubin, then maximizing the cycle-time spacing between delivery of each such very-short-duration burst pulses ideally to match the actual bilirubin migratory rates of the target tissue so as to eliminate the extremely high-ratio presence of untherapeutically excessive total light irradiance dose that occurs in treatment with all conventional phototherapy apparatuses and processes in prior use.

126. A phototherapy apparatus and method characterized by short burst durations of light exposure representing a minor, small fraction of the repeat cycle-time, each light exposure duration being minimally above the nanoseconds-time-period threshold requirement for the chemical photoisomerization of bilirubin to occur, each subsequent pulse being spaced to match the migratory rate of bilirubin that is characteristic as a migratory rate for the particular tissue that is being targeted for phototherapy irradiation.

127. A phototherapy apparatus and method whereby light is delivered to the patient in flashes or burst pulses greatly shortened in duration down to tiny fractions of a second, to approach the mere nanoseconds-long time period actually required to cause the molecular-level therapeutic photoisomerization of bilirubin.

128. The phototherapy apparatus and method of Claim 127 whereby said flashes of light are repeated only often enough to accommodate or match the actual bilirubin migratory rates of the particular tissue being targeted, the short-duration flashes spaced in time as far apart as possible in sequential cycling to eliminate unnecessary exposure and thus reduce total light irradiance dose to a level below that of conventional phototherapy units.

129. The phototherapy apparatus and method of Claim 128 with the additional utilization of greatly increased intensity of light for deeper penetration into, and more extensive simultaneous coverage of, patients' target tissue to cause a greater number of bilirubin molecules to simultaneously undergo molecular photoisomerization.

130. A phototherapy method or device whereby the light pulse duration is less than 50% of its cycle-time.

131. The phototherapy method or device of Claim 130 whereby the light pulse duration is less than 49% of its cycle-time.

132. The phototherapy method or device of Claim 131 whereby the light pulse duration is less than 48% of its cycle-time.

133. The phototherapy method or device of Claim 132 whereby the light pulse duration is less than 45% of its cycle-time.

134. The phototherapy method or device of Claim 133 whereby the light pulse duration is less than 40% of its cycle-time.

135. The phototherapy method or device of Claim 134 whereby the light pulse duration is less than 30% of its cycle-time.

136. The phototherapy method or device of Claim 135 whereby the light pulse duration is less than 20% of its cycle-time.

137. The phototherapy method or device of Claim 136 whereby the light pulse duration is less than 10% of its cycle-time.

138. The phototherapy method or device of Claim 137 whereby the light pulse duration is less than 5% of its cycle-time.

139. The phototherapy method or device of Claim 138 whereby the light pulse duration is less than 4% of its cycle-time.

140. The phototherapy method or device of Claim 139 whereby the light pulse duration is less than 3% of its cycle-time.

141. The phototherapy method or device of Claim 140 whereby the light pulse duration is less than 2% of its cycle-time.

142. The phototherapy method or device of Claim 141 whereby the light pulse duration is less than 1% of its cycle-time.

143. The phototherapy method or device of Claim 142 whereby the light pulse duration is less than 0.5 % of its cycle-time.

144. The phototherapy method or device of Claim 143 whereby the light pulse duration is less than 0.3 % of its cycle-time.

145. The phototherapy method or device of Claim 144 whereby the light pulse duration is less than 0.2 % of its cycle-time.

146. The phototherapy method or device of Claim 145 whereby the light pulse duration is less than 0.1 % of its cycle-time.

147. The phototherapy method or device of Claim 146 whereby the light pulse duration is less than 0.01 % of its cycle-time.

148. The phototherapy method or device of Claim 147 whereby the light pulse duration is less than 0.001 % of its cycle-time.

149. The phototherapy method or device of Claim 148 whereby the light pulse duration is less than 0.0001 % of its cycle-time.

150. The phototherapy method or device of Claim 149 whereby the light pulse duration is less than 0.00001 % of its cycle-time.

151. The phototherapy method or device of Claim 150 whereby the light pulse duration is less than 0.000001 % of its cycle-time.

152. The phototherapy method or device of Claim 151 whereby the light pulse duration is less than 0.0000001 % of its cycle-time.

153. The phototherapy method or device of Claim 152 whereby the light pulse duration is less than 0.00000001 % of its cycle-time.

154. The phototherapy method or device of Claim 153 whereby the light pulse duration is less than 0.000000001 % of its cycle-time.

155. The phototherapy methods, processes, or devices of Claims 1 - 154 whereby a series of closely-spaced flashes are placed together before each blackout period of the overall process cycle-time, where each such cycle-time would comprise a) multiple flash or pulse components whereby the group of such closely-spaced flashes or pulses occurred over a period of minutes or seconds or a fraction of a second, and b) the preceding being followed by the blackout period of said overall process cycle-time.

156. The phototherapy methods, processes, or devices of Claim 155 whereby the duration of said blackout period exceeds the time during which said group of such closely-spaced multiple flashes or pulses occur.

157. The phototherapy methods, processes, or devices of Claim 156 whereby the duration of said blackout period exceeds the cumulative time of actual light emission of said group of such closely-spaced multiple flashes or pulses.

158. The phototherapy methods, processes, or devices of Claims 155 - 157 whereby said group of such closely-spaced multiple flashes or pulses occur within a minor cycle-time or minor cycle-times that exists within an overall process cycle-time that includes a the major blackout period.

159. The phototherapy methods of Claims 1 - 158 whereby the light is directed for the photoisomerization of bilirubin.

160. The phototherapy methods of Claim 159 whereby the light is directed for the treatment of hyperbilirubinemia.

161. The phototherapy methods of Claims 160 whereby the light is directed for the treatment of hyperbilirubinemia in neonates.

162. The phototherapy methods, processes, or devices of Claims 1 - 161 whereby the light source used is of a safe type that includes in its emission sufficient energy levels in the appropriate wavelength range to cause therapeutic photoisomerization of bilirubin.

163. The phototherapy methods, processes, or devices of Claims 1 - 162 whereby the light source includes light from a xenon gas tube.

164. The phototherapy methods, processes, or devices of Claims 1 - 161 whereby the light source includes light from a gas tube.

165. The phototherapy methods, processes, or devices of Claims 1 - 161 whereby the light source includes laser-source light.

166. The phototherapy methods, processes, or devices of Claims 1 - 161 whereby the light source includes light-emitting-diode light.

167. The phototherapy methods, processes, or devices of Claims 1 - 161 whereby the light source includes light from one or more electronic flash units.

168. The phototherapy methods, processes, or devices of Claims 1 - 167 whereby the light source includes light from one or more light sources.

169. The phototherapy methods, processes, or devices of Claims 1 - 167 whereby the light source includes light from one or more light source types.

170. The phototherapy methods or devices of Claims 1 - 168 whereby the light source used includes light from a xenon tube type of light source.

171. The phototherapy device of Claims 1 - 170 whereby the light source used is or includes a photographic-type electronic flash unit adapted for use as a phototherapy instrument.

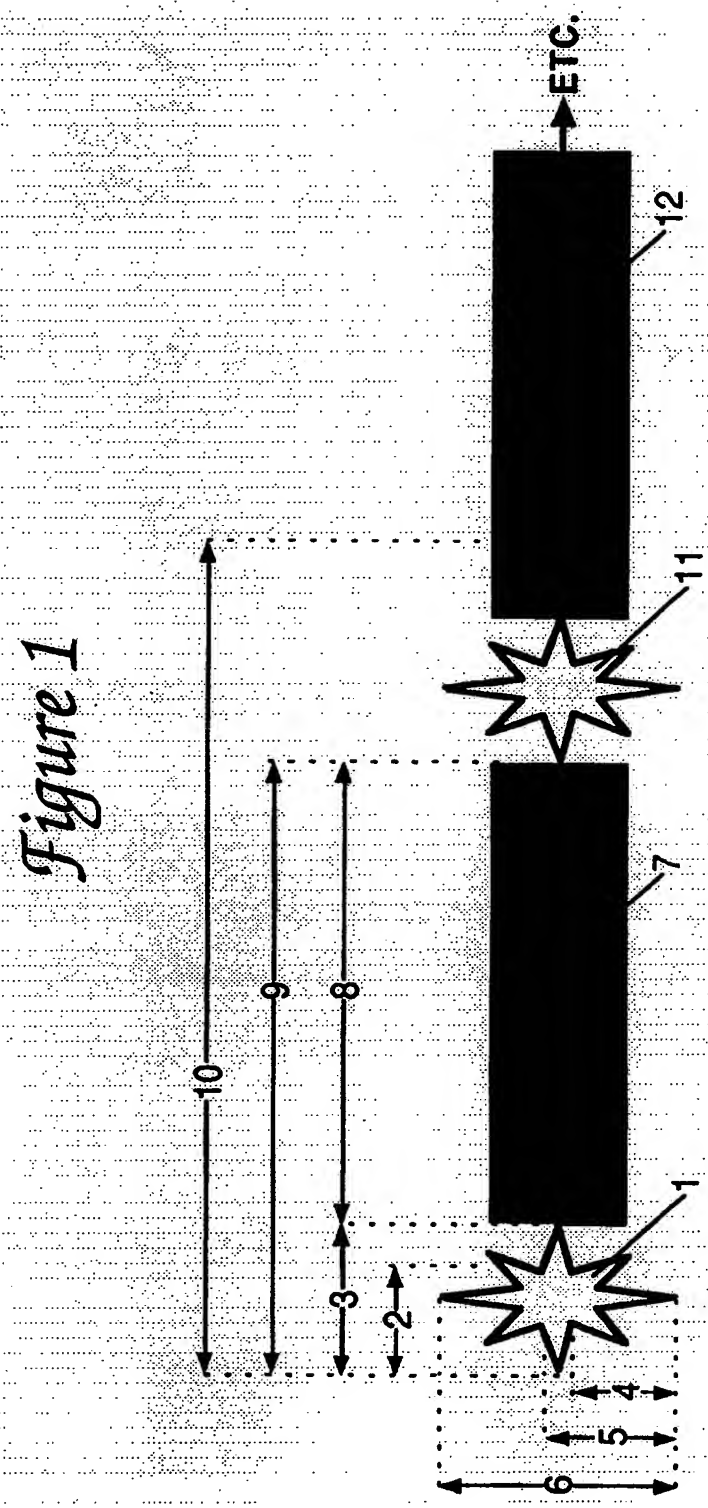


Figure 1

Figure 2a

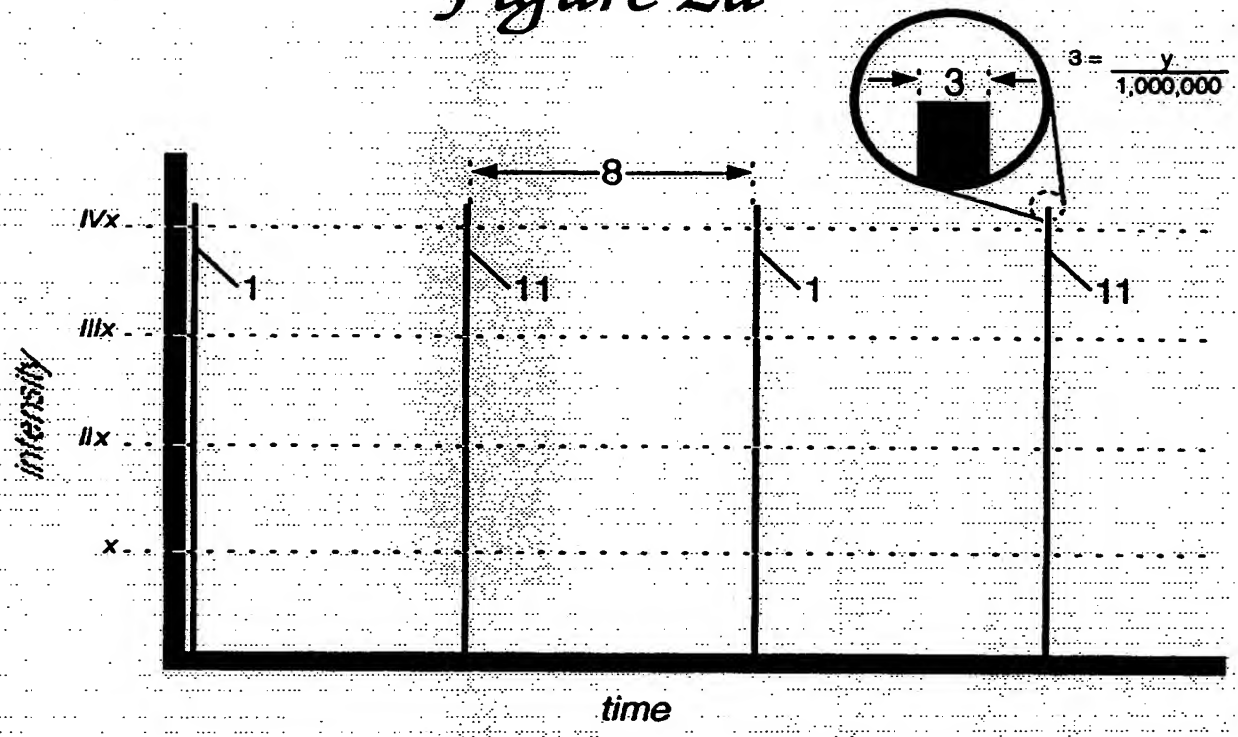
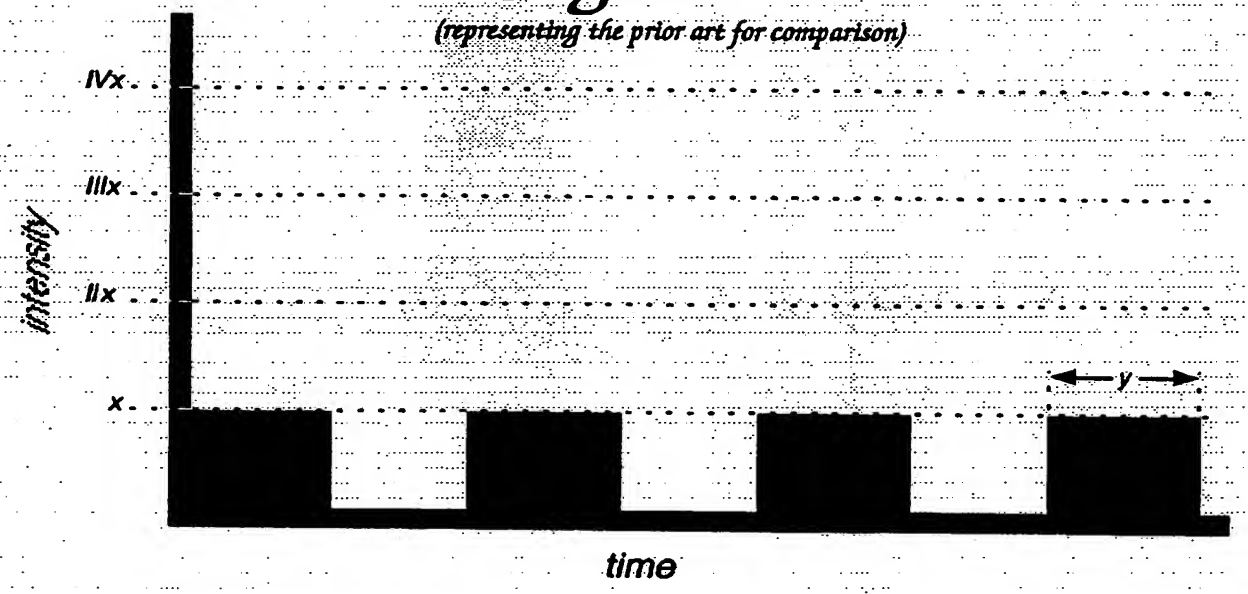


Figure 2b

(representing the prior art for comparison)




3
.001 second flash of light
8
30-minute period without phototherapeutic light

Figure 3

Figure 4

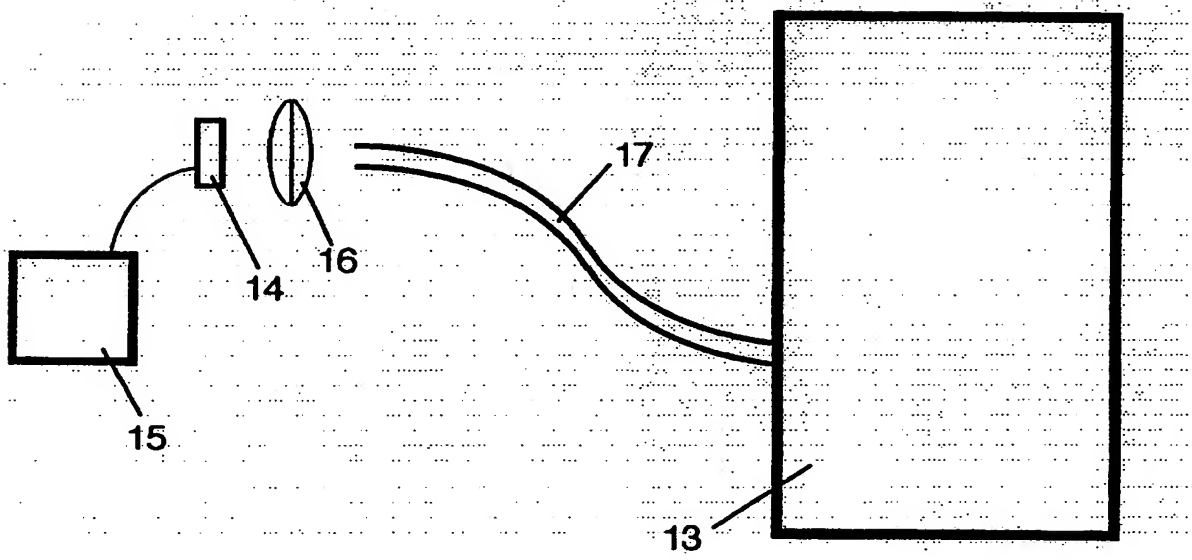


Figure 5

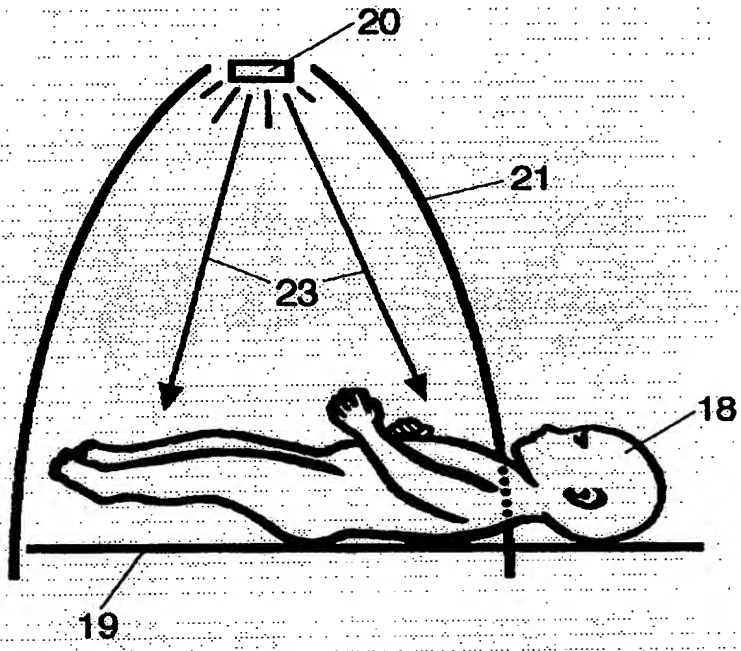


Figure 6